Pricing Issues for the Procurement of Diagnostics

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Agenda

Equipment procurement methodologies

Other cost considerations

Example

Diagnostic systems require significant expenditure for lab equipment, commodities and service

Capital Expenditure

- Laboratory infrastructure to house and ensure optimal use of equipment (e.g., air-conditioning, etc.)
- Proprietary laboratory equipment (e.g. DNA amplification instrument)
- Non-proprietary lab equipment (e.g. centrifuges, bio-safety hoods)

Proprietary Laboratory Items (Reagents and Consumables)

Non-Proprietary Laboratory Items (Generic Consumables)

Sample Collection Materials

Service and maintenance, software upgrades and staff training

There are three general methods of procuring lab equipment

1. **Outright Equipment Purchase**
2. **Equipment Lease**
3. **Reagent Rental**

Outright Equipment Purchase

1

Terms

Proprietary equipment is purchased separately from any other item such as reagents and proprietary consumables, service and maintenance, software upgrades, etc.

Pros	Cons
• **Ownership** of equipment • More likely to conform with country or donor equipment procurement policies • More **transparent pricing** of instrument and additional items	• High upfront **capital expenditure** • **High administrative costs** of managing (signing, monitoring, renewal) separately **Service & Maintenance (S&M)** • **High risk of service interruptions** when S&M contracts are overlooked • **Software upgrades** are an **additional cost**

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Equipment Lease

2

Terms

Proprietary equipment is leased through regular payments over a fixed time period with the option to purchase the equipment at the end of the contract term at an agreed value (usually $1).

Pros	Cons
• **Lower upfront investment** • **Service and maintenance included** in the terms of the lease	• **No ownership** of equipment • **Higher overall cost of instrument and S&M** due to the cost of financing (about 6-8%)

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Reagent Rental

3

Terms

Vendor supplies the lab equipment, reagents & proprietary lab consumables, training, service and maintenance and software upgrades as part of **one cost per test**, conditional on a testing volume commitment.

Pros

- **Lower upfront investment**
- **No administrative costs associated with** managing separately **S&M contracts** (S&M included in the price per test)
- **Higher flexibility** to respond to changes in technology (3-5 year contracts)
- **Higher incentive for suppliers to timely service** non-functioning equipment

Cons

- **No ownership** of equipment
- **Possible higher overall cost per test** due to the cost of financing (revenues are postponed)
- **Complexity in negotiating a fair price** (price premium should reflect expected testing volumes)
- **Volume commitment**

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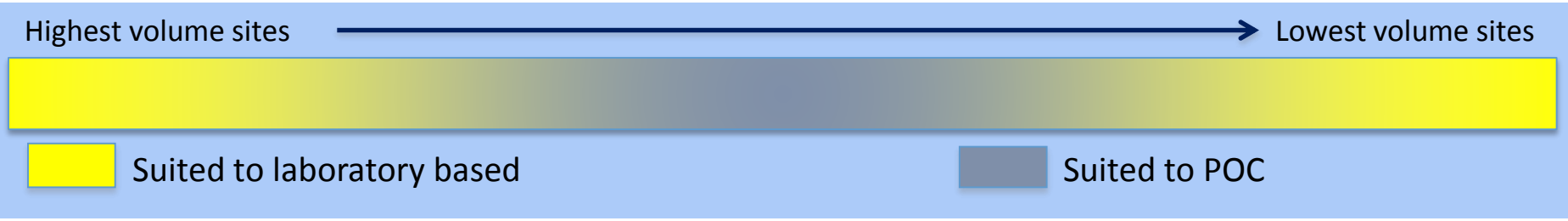
There is a sweet spot for sites where laboratory based and POC testing make economic sense based on throughput, cost and complexity



Actual share of the market will depend on:

1. **Country preference**
   Leverage current laboratory based platforms?
2. **Price points for device/reagents**
   Cost of POC test vs laboratory based + sample transport
3. **Throughput of POC/near-POC**
   # of machines required to meet patient need vs. burden on health workers
4. **Guidelines on DBS**
   Without DBS, laboratory based may not be able to reach peripheral sites

Sample: COUNTRY A – LESS DECENTRALIZATION: Most patients seek care at District Hospitals

Poor on-site CD4 coverage

Medium on-site CD4 coverage

Good on-site CD4 coverage

Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	17%	13%	4%	**34%**
10-20 Patients per Day	<1%	17%	8%	**26%**
5-10 Patients per Day	<1%	11%	5%	**16%**
0-5 Patients per Day	0%	8%	16%	**24%**
TOTAL	**18%**	**49%**	**33%**	**100%**

Sample: COUNTRY B – HIGH DECENTRALIZATION: Most patients seek care at Health Centers

Poor on-site CD4 coverage

Medium on-site CD4 coverage

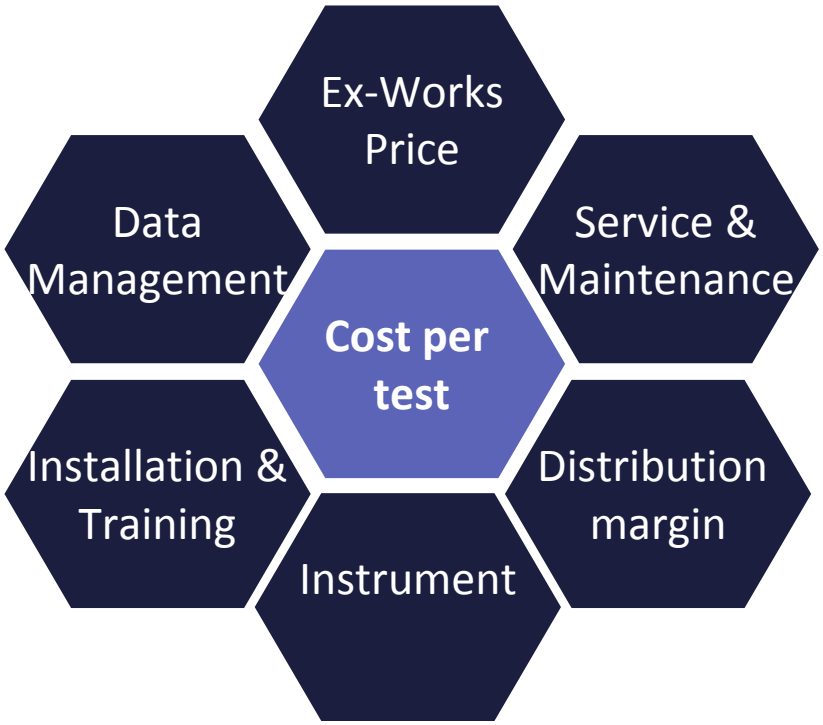
Good on-site CD4 coverage

Market Segmentation by facility level and pre-ART patient population

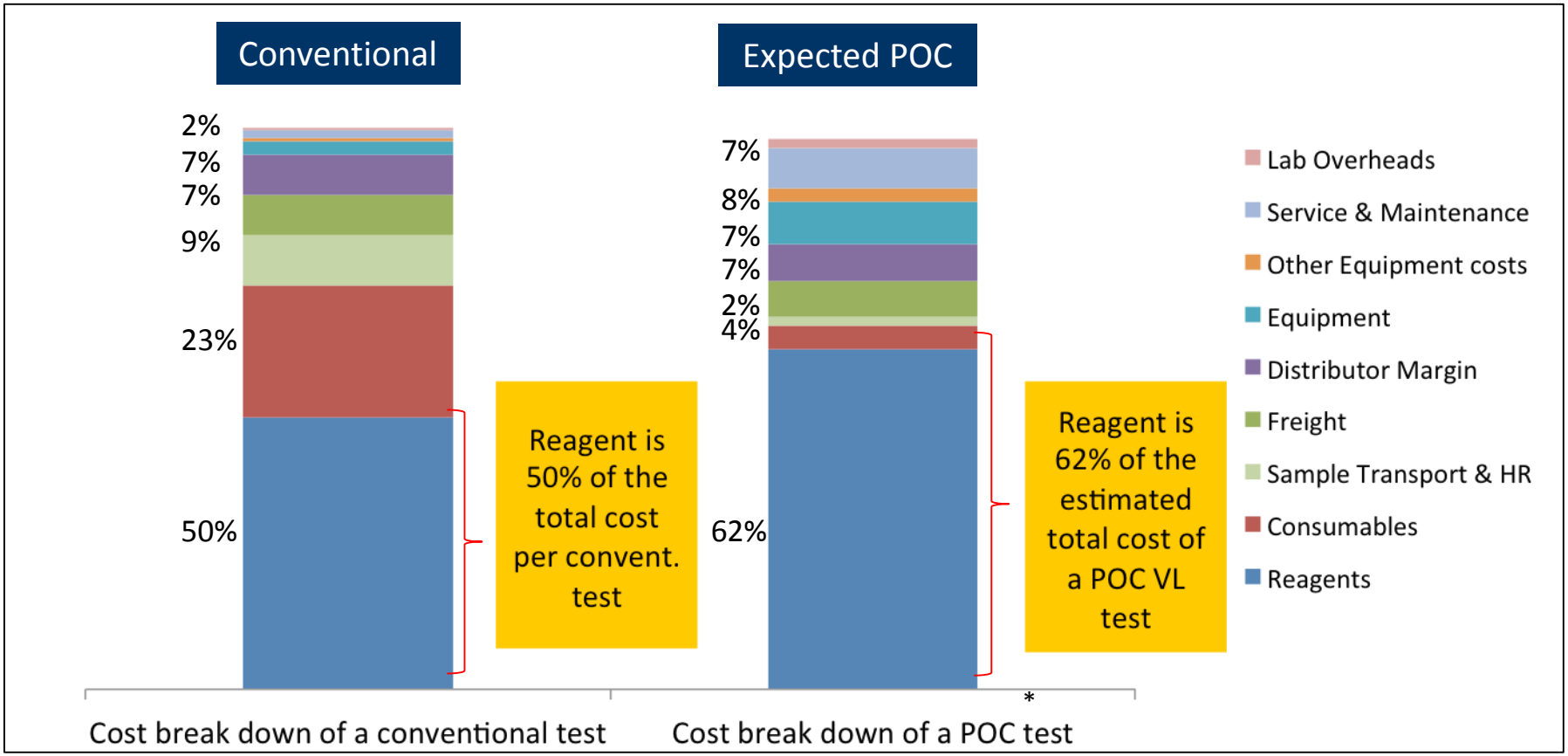
Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	9%	3%	25%	**37%**
10-20 Patients per Day	3%	9%	11%	**23%**
5-10 Patients per Day	0%	6%	8%	**14%**
0-5 Patients per Day	0%	4%	22%	**26%**
TOTAL	**12%**	**22%**	**66%**	**100%**

Beyond the price of reagents and equipment

The price of reagents is only one of many components that should be discussed with suppliers during the negotiation phase



Viral load is impacted by an array of costs



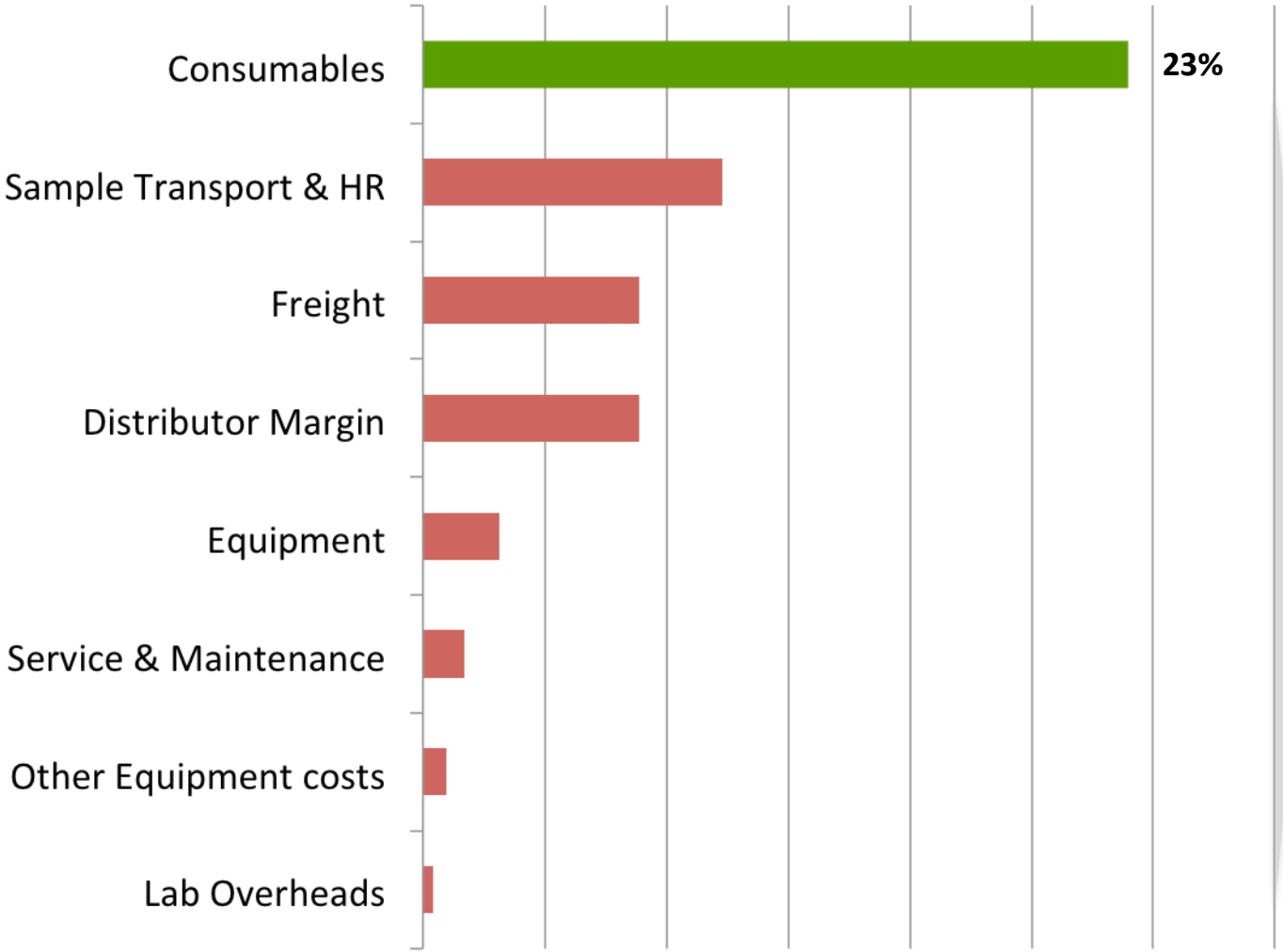
Reagents are but one of many key contributors to cost that must be considered when planning the scale up of viral load

Source: Estimated based on historical procurement experience and country data

** Expected costs based on experience*

Consumables are the second highest cost drivers for viral load testing

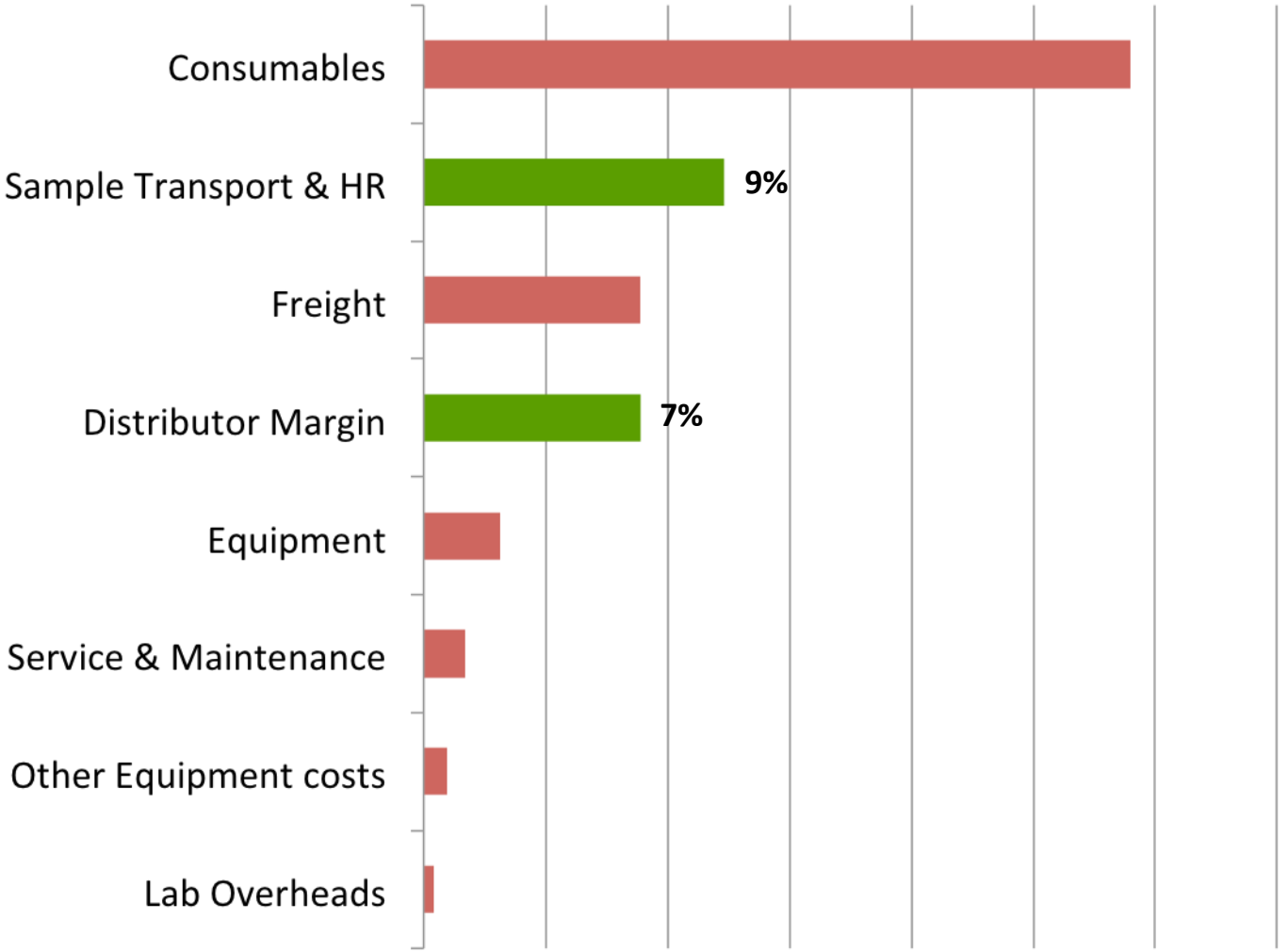
- Conventional VL testing cost components other than reagents -



The procurement of bundles for sample collection and for the lab rather than individual units ensures the use of high quality items and reduces wastage. Can use EID experience of consumable bundling.

VL Cost Breakdown – Sample Transportation and Distributor Margin

- Conventional VL testing cost components other than reagents -

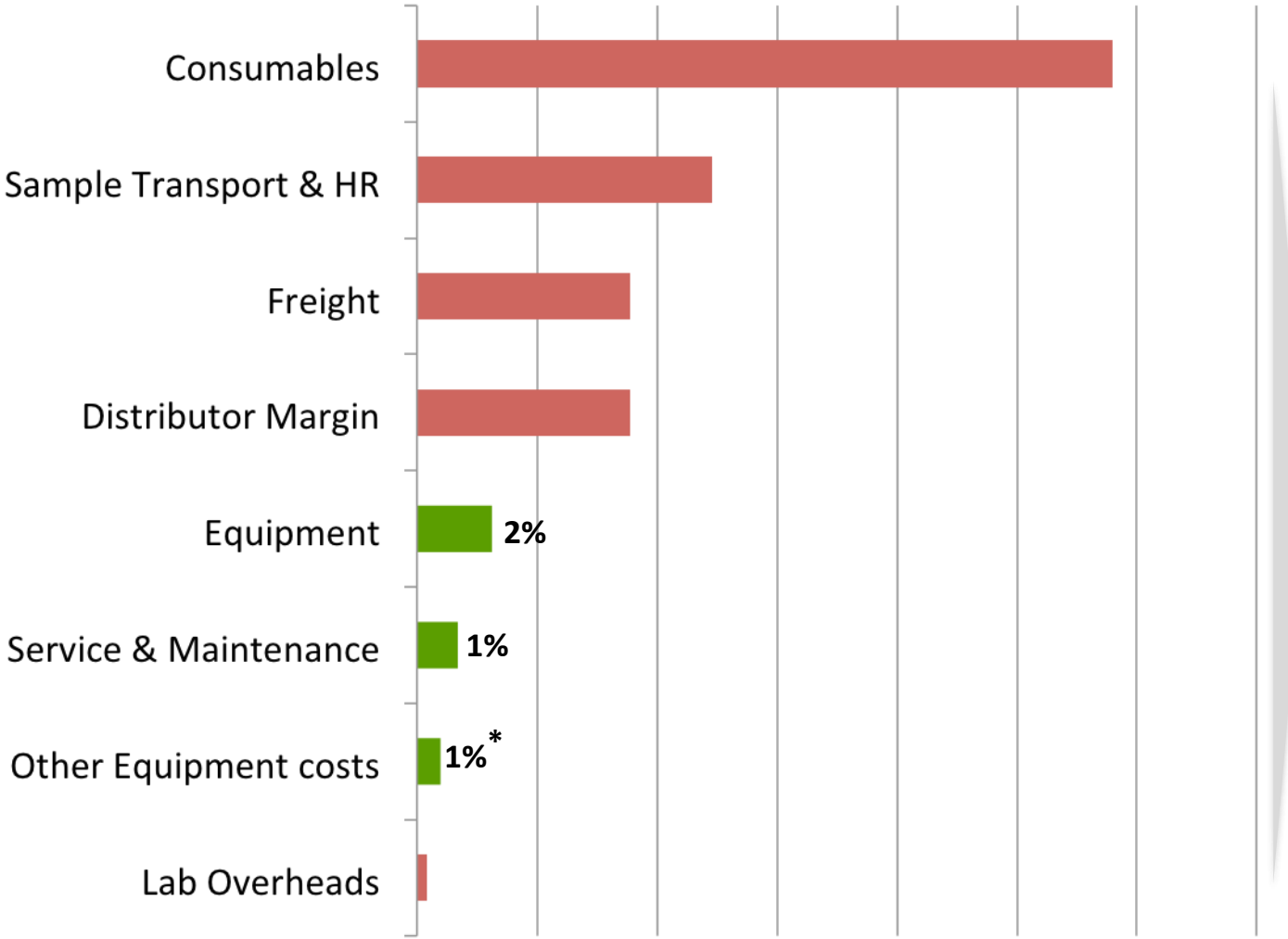


Several countries have established sample transportation networks but these are generally underutilized. Sharing costs across tests or diseases can reduce cost per test.

Distribution margin varies highly from country to country and, in some cases, can significantly impact cost per test. More transparency is needed to maintain distribution margins within reasonable ranges.

VL Cost Breakdown – Equipment and Service & Maintenance

- Conventional VL testing cost components other than reagents -



Assumptions: VL machines amortize over 8 years

Many countries experience low utilization of DNA PCR machines which represents an opportunity to leverage existing infrastructure and service (e.g. EID) to jumpstart viral load.

Conventional and some of the planned POC instruments are multiplex allowing for cost sharing across test and disease areas.

Service and maintenance has been a thorn. Community must include long term service in planning.

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Example: CD4

"Our initial engagement in (a high-volume country) with reagent rental was for CD4 machines. The contract had the following clauses:

•Equipment was a reagent rental with volume commitment of $X.XX per test, inclusive of all consumables (minus controls and stabilised blood controls) and service and maintenance

•Stipulated volume commitment across 3 years at a guarantee of 72,000 tests annually. If volumes are not met, the contract allows the manufacturer to revise pricing to recuperate the costs incurred during the period of the contract

•Device belongs to the manufacturer during the period of the contract. In some MoH set ups, the idea of not owing the equipment is not a feasible solution

•Contract stipulates that the manufacturer will provide free upgrades on the existing equipment, and at the end of the contract there is a possibility to re-negotatiate for placement of newer technology if available.

•Service bundled in the cost of the test which makes equipment downtime the problem of the manufacturer

This type of contract is advantageous in a high volume country where the volume guarantee is feasible to achieve."

Conclusions/Thoughts

- Various contexts will require various procurement methodologies.
- Total cost of ownership calculation purchase vs bundled is a must.
  - Highly sensitive to price, volumes. Accurate forecasting imperative
  - May be more expensive to bundle but are advantages worth additional cost?
- Placement and subsequent utilization of equipment can be an important factor.
- Other cost and procurement related issues, including procurement of services, impact total cost.
  - Bundling other products and/or services outside of equipment and reagents only
  - Longer term service contracts standard for all equipment procurement